REMARKS

The Examiner has objected to the specification because the continuing data needs to be updated. The specification has been amended in response to the Examiner's objection.

The Examiner has objected to the Information Disclosure Statement, filed on November 18, 2002, in the above-captioned application. The references not of record in the grandparent application, U.S. application serial number 08/916,490, are provided with the Transmittal of References submitted herewith to respond to the Examiner's objection.

The Examiner has rejected claims 1-7 and 11-13 for alleged statutory double patenting under 35 U.S.C. § 101 over claims 1-3, 5-7, 19, 22, 26, and 29 of U.S. Patent No. 6,206,931. It is respectfully pointed out that the above-captioned application was filed to provoke an interference with U.S. Patent No. 6,206,931. The Examiner's attention is directed to the "Notice of Claims Copied From U.S. Patent No. 6,206,931" filed by Applicants in the above-captioned application on May 20, 2002. Furthermore, U.S. Patent No. 6,206,931 and the above-captioned application are assigned to different entities. U.S. Patent No. 6,206,931 is assigned to Cook Incorporated, Cook Biotechnology, Inc., and MED Institute, Inc., whereas the above-captioned application is assigned to Purdue Research Foundation. Accordingly, there cannot be a double patenting issue and the rejection in the instant case is believed to be improper. Withdrawal of the rejection of claims 1-7 and 11-13 for alleged statutory double patenting over claims 1-3, 5-7, 19, 22, 26, and 29 of U.S. Patent No. 6,206,931 is therefore respectfully requested.

The Examiner has rejected claims 8, 10, and 16-20 under the judicially created doctrine of obviousness-type double patenting as allegedly being unpatentable over claims 10 and 34-38 of U.S. Patent No. 6,206,931. As indicated above in Applicants' response to the Examiner's statutory double patenting rejection of claims 1-7 and 11-13, the above-captioned application was filed to provoke an interference with U.S. Patent No. 6,206,931, which is assigned to several different entities none of which are Purdue Research Foundation. Accordingly, there cannot be a double patenting issue and the rejection is believed to be

improper. Withdrawal of the rejection of claims 8, 10, and 16-20 for alleged non-statutory double patenting over claims 10 and 34-38 of U.S. Patent No. 6,206,931 is therefore respectfully requested.

The Examiner has rejected claim 9 under the judicially created doctrine of obviousness-type double patenting as allegedly being unpatentable over claim 20 of U.S. Patent No. 6,206,931 in view of Kemp (U.S. Patent No. 5,460, 982). As indicated above in Applicants' responses to the Examiner's statutory and non-statutory double patenting rejections, the above-captioned application was filed to provoke an interference with U.S. Patent No. 6,206,931, which is assigned to several different entities none of which are Purdue Research Foundation. Accordingly, there cannot be a double patenting issue and the rejection is believed to be improper. Withdrawal of the rejection of claim 9 for alleged non-statutory double patenting over claim 20 of U.S. Patent No. 6,206,931 in view of Kemp (U.S. Patent No. 5,460,982) is therefore respectfully requested.

The Examiner has rejected claims 1-7 and 11-13 under 35 U.S.C. § 102(f) as allegedly being anticipated by claims 1-3, 5-7, 10, 22, 26, and 29 of U.S. Patent No. 6,206,931. As indicated above in Applicants' responses to the Examiner's statutory and non-statutory double patenting rejections, the above-captioned application was filed to provoke an interference with U.S. Patent No. 6,206,931. Furthermore, it is respectfully pointed out that U.S. Patent No. 6,206,931 and the above-captioned application each claim priority to the same two provisional applications, namely, U.S. Provisional Patent Application Nos. 60/024,542 and 60/024,693, filed August 23, 1996 and September 6, 1996, respectively. As the effective filing dates for the above-captioned application and U.S. Patent No. 6,206,931 are identical, there cannot be an anticipation issue. Accordingly, the Examiner's rejection under 35 U.S.C. § 102(f) is believed to be improper. Withdrawal of the rejection of claims 1-7 and 11-13 under 35 U.S.C. § 102(f) as allegedly being anticipated by claims 1-3, 5-7, 10, 22, 26, and 29 of U.S. Patent No. 6,206,931 is therefore respectfully requested.

Further, Applicants do not understand the reference to § 102(f) and request

clarification. Applicants' wish to point the Examiner's attention to the executed oath and declaration filed in response to a Notice to File Missing Parts in the above-captioned application.

The Examiner has rejected claims 8, 10, and 16-20 under 35 U.S.C. § 103(a) as allegedly being obvious, and therefore unpatentable, over U.S. Patent No. 6,206,931. As indicated above in Applicants' responses to the Examiner's statutory and non-statutory double patenting rejections and the rejection made under 35 U.S.C. § 102(f), the above-captioned application was filed to provoke an interference with U.S. Patent No. 6,206,931. Furthermore, it is again respectfully pointed out that U.S. Patent No. 6,206,931 and the above-captioned application each claim priority to the same two provisional applications, namely, U.S. Provisional Patent Application Nos. 60/024,542 and 60/024,693, filed August 23, 1996 and September 6, 1996, respectively. As the effective filing dates for the above-captioned application and U.S. Patent No. 6,206,931 are identical, there cannot be an obviousness issue. Accordingly, the Examiner's rejection under 35 U.S.C. § 103(a) is believed to be improper. Withdrawal of the rejection of claims 8, 10, and 16-20 under 35 U.S.C. § 103(a) as allegedly being obvious, and therefore unpatentable, over U.S. Patent No. 6,206,931 is therefore respectfully requested.

The Examiner has also rejected claims 16-20 under 35 U.S.C. § 102(b) as allegedly being anticipated by Kemp (U.S. Patent No. 5,460, 962), or, alternatively, under 35 U.S.C. § 103(a) as allegedly being obvious over Kemp (U.S. Patent No. 5,460, 962). Although Kemp discloses a sterilized tissue matrix that can be made of submucosa tissue by treating the tissue with a peracetic acid, the Examiner's assertion that Kemp utilizing the same tissue in the same way as Applicants results in tissue that "necessarily has the claimed endotoxin level, tela submucosa and residual contaminants as claimed" is based on the doctrine of inherency. Such a basis can be relied upon only if it is clear that following the teachings of Kemp will necessarily lead to the elements of the instant claims. In view of the direct comparative testing set forth in the above-captioned application, specifically, that described in Example 5/paragraph [0090], it is clear that Kemp does not necessarily result in the claimed features, most notably an endotoxin level of less than 12 endotoxin units per gram. Further, the Examiner's assertion that "the

difference between Kemp and the claimed device are at most nominal" is inconsistent with the comparative testing results set forth in Example 5/paragraph [0090] of the above-captioned application, which indicate a difference of at least two orders of magnitude in endotoxin levels between Kemp and the claimed device. Accordingly, there is no basis or sound technical reasoning upon which to conclude that the claimed features would necessarily, and therefore obviously, result from Kemp. Withdrawal of the rejection of claims 16-20 under 35 U.S.C. § 102(b) as allegedly being anticipated by Kemp, and under 35 U.S.C. § 103(a) as allegedly being obvious over Kemp (U.S. Patent No. 5,460,962) is therefore respectfully requested.

The Examiner is respectfully directed to the prosecution file history of U.S. Patent No. 6,206,931, wherein essentially identical arguments were made in response to similar Kemp (U.S. Patent No. 5,460,962)-based 35 U.S.C. §102 and §103 rejections, and these arguments resulted in allowance of claims 34-38, claims that are virtually identical in scope to claims 16-20 in the above-captioned application.

The Examiner has objected to claims 14 and 15 as being dependent upon a rejected base claim, but has indicated these claims to be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims. Applicants acknowledge, with appreciation, that claims 14 and 15 represent allowable subject matter. However, the base claim from which claims 14 and 15 depend, i.e., claim 1, has been rejected by the Examiner in view of U.S. Patent No. 6,206,931, with which Applicants seek to provoke an interference. Accordingly, no amendments to claims 14 and 15 (or any other claims) have been made herein.

The Examiner has requested that Applicants provide a list of all copending applications that set forth subject matter similar to the claims of the above-captioned application, as well as a copy of co-pending claims. Co-pending U.S. Patent Application Nos. 10/744,420 and 10/811,343, the claims of which are submitted as Appendix A and Appendix B, respectively, to this response, set forth such subject matter. U.S. Patent Application No. 10/744,420 and U.S. Patent Application No. 10/811,343 are related to the '931 patent.

Respectfully submitted,

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